

## MDL-1355 TERM SHEET

The Plaintiffs' Steering Committee (PSC) and defense counsel have conferred respecting end game planning committee matters.

They have reached a tentative agreement for resolution of cases pending in this MDL proceeding. This is the agreement:

### 1. THE PROGRAM

A. The PSC and the defendants will establish a global mediation and resolution Program (hereafter the "Program") whose purpose is to establish a system, subject to this court's jurisdiction, whereby the claims of plaintiffs to a recovery will be reviewed and resolved by a panel of physicians.

This Program will be in lieu of any further litigation by the plaintiffs respecting their acquisition or use of Propulsid.

B. The Program will not become effective unless and until: (1) 85% of the plaintiffs who are maintaining wrongful death actions in cases pending in this court and 75% of the remaining plaintiffs who have cases pending in this court for claims other than wrongful death have agreed in writing by completion and service of an Enrollment Form as described in Section 21 to become part of the Program and to be bound by its terms and (2) the agreements described in 1(C) have also been reached. These three components shall be known as the "minimum enrollment". (As of the present time there are approximately 4000 plaintiffs whose cases are pending in federal courts. Not all of them have had their cases transferred to this court although those transfers are in process. Approximately 300 of the 4000 plaintiffs are maintaining wrongful death actions.) "Pending in this court" shall mean cases filed in or removed to federal court before February 1, 2004 which were then pending in the MDL Court or were in the course of being transferred or hereafter are transferred to this court by the MDL Panel. Plaintiffs and claimants are limited to citizens or residents of the United States.

"Plaintiffs" in this agreement means all persons who claim a loss as a result of the death or injury claimed to have resulted from use of Propulsid. Thus spouses qualify as one plaintiff; all persons who claim any loss as a result of the death of a person qualify as one plaintiff. Thus, spouses, children and/or heirs, together with the person who sustained the claimed injury or death, constitute a single plaintiff for purposes of Section 1.

Once the minimum enrollment requirements described above and in Section 21 have been reached, the Program enrollment shall remain open for six additional months. As the percentages of plaintiffs who enroll during this additional six-month period reach the levels beyond the 85% and 75% described in this Section, the settlement fund shall be increased in accordance with the terms of Section 3(B). The parties reserve the right to agree to extend this additional period beyond the six months.

C. In addition to the plaintiffs identified above, this Program will not become effective unless and until counsel for no less than 12,000 persons who have signed tolling agreements respecting their potential claims against the defendants (hereafter "claimants") and who are citizens or residents of the United States agree in writing by completion and service of an Enrollment Form as described in Section 21 on behalf of their clients to become part of the Program and to be bound by its terms. As of the present time there are approximately 36,000 such persons including the parties in the Achord suit filed in the Eastern District of Louisiana. Defendants will supply the PSC with a report identifying tolling agreement claimants. The 12,000 persons described herein shall include all plaintiffs in the Achord suit. Within 10 days of execution of this document, defense counsel shall deliver to the PSC listings of all death and non-death plaintiffs in the MDL and claimants on tolling agreements (including those in the Achord suit). The listings shall include, as appropriate and available, the name, address, email address, telephone number and case docket information or other identifying court information for each plaintiff, each claimant and the attorney for each plaintiff and each claimant. These lists shall be updated on a regular basis and provided to the PSC.

D. The agreements described herein shall be signed by counsel for the plaintiffs or claimants who shall represent that they have full authority from their clients to enter into the agreement.

E. The Program will be established pursuant to an order of the MDL Court. It will be administered by the Special Master appointed by the MDL court pursuant to Federal Rule of Civil Procedure 53. The Special Master shall have the authority to engage support personnel to assist in management of the Program and shall be required to render reports to the MDL court from time to time respecting the management of the Program, including allowance and disallowance of claims.

F. The terms, conditions and qualifications of the Program will be as are set forth in the "Propulsid MDL 1355 Settlement Program" (hereafter the "Program") attached hereto as Exhibit A.

## 2. SPECIAL MASTER AND MEDICAL PANEL

A. Eligibility for payment will be based on medical records, as is set forth in more detail in the Program.

B. The Medical Panel described herein shall have the sole and exclusive authority to determine eligibility for payment under the Program or non-eligibility under the Program.

C. Once the Medical Panel has made a determination that a plaintiff or claimant is eligible for payment and has determined the category in which the plaintiff or claimant falls, the Special Master shall have sole and exclusive authority to determine the sum to be awarded to that person.

D. The determinations made by the Medical Panel and the Special Master are final determinations and, other than as set forth in Louisiana Civil Code Article 1953, shall not be subject to review or appeal, whether by mandamus or otherwise, in any court by the plaintiffs, the claimants or the defendants.

### 3. SETTLEMENT AND ADMINISTRATIVE FUNDS

A. The parties agree that the defendants shall pay the sums designated below for the settlement and administrative funds and for the payment described in Section 19.

B. The settlement fund shall be funded by the defendants and shall be no less than \$69,500,000 and no more than \$90,000,000. The fund shall be \$69,500,000 if 85% of the plaintiffs described in Section 1(B) who are maintaining death cases and 75% of the plaintiffs who are maintaining non-death cases and the 12,000 persons described in Section 1(C) agree in writing through their counsel to enter into the agreement, all as set forth in Section 1(D).

In the event more than 85% of the death case plaintiffs agree in writing through their counsel to enter into the agreement set forth in Section 1(D), then the settlement fund shall be increased by an additional sum as follows:

Percentage enrolling	Additional sum to be paid to settlement fund
86%	\$700,000
87%	\$700,000
88%	\$700,000
89%	\$700,000
90%	\$700,000
91%	\$900,000
92%	\$900,000
93%	\$900,000
94%	\$900,000
95%	\$900,000
96%	\$1,700,000
97%	\$1,700,000
98%	\$1,700,000
99%	\$1,700,000
100%	\$1,700,000

Accordingly, if there is 100% enrollment of the death case plaintiffs, the additional sum to be paid to the settlement fund will total \$16,500,000.

In the event more than 75% of the non-death case plaintiffs agree in writing through their counsel to enter into the agreement set forth in Section 1D, then the settlement fund shall be increased by an additional sum as follows:

Percentage enrolling	Additional sum to be paid to settlement fund
76%	\$50,000
77%	\$50,000
78%	\$50,000
79%	\$50,000
80%	\$50,000
81%	\$50,000
82%	\$50,000
83%	\$50,000
84%	\$50,000
85%	\$50,000
86%	\$100,000
87%	\$100,000
88%	\$100,000
89%	\$100,000
90%	\$100,000
91%	\$200,000
92%	\$200,000
93%	\$200,000
94%	\$200,000
95%	\$200,000
96%	\$400,000
97%	\$400,000
98%	\$400,000
99%	\$400,000
100%	\$400,000

Accordingly, if there is a 100% enrollment of the non-death case plaintiffs, the additional sum to be paid to the settlement fund will total \$4,000,000.

There shall be no pro rata increased payment to the Settlement Fund if the number of plaintiffs who agree in writing through their counsel to enter into the agreement are greater than any of the above described levels. The increased payment is only due if the actual level is reached.

C. The parties have evaluated the expected costs of the administrative fund, discussed them with each other and have anticipated that the costs will not exceed \$15,000,000. The defendants have, nevertheless, agreed to fund the administrative fund in the amount of \$15,000,000. In the

unlikely event it appears during the administration of the Program that the costs of the administrative fund might exceed \$15,000,000, either party shall bring the matter to the attention of the MDL Court, which shall have the authority to modify the Program to ensure that the administrative fund does not exceed \$15,000,000. Under no circumstances shall the defendants have any obligation to pay more than \$15,000,000 for the administrative fund.

D. Counsel for plaintiffs described in Section 1(B) shall not be permitted to enroll less than 100% of the MDL plaintiffs they represent in those cases. Counsel for plaintiffs within the meaning of this Section are defined to be those who were counsel of record per pleadings filed before February 1, 2004. Counsel who are members of the PSC shall be required to enroll in the Program all the claimants they represent who are under tolling agreements as described in Section 1(C).

E. The parties wish to have the settlement fund maintained in as secure a manner as possible so that those funds will be available to be paid to the plaintiffs and claimants who qualify for payment. They will consult as to the bank depository or other prudential financial institution which will be chosen to hold those funds and will also consult as to the form of prudent investment vehicles to be used for investment of the funds. The PSC shall designate the institution subject to defendants' agreement. Once a tentative decision as to the institution and the form of the investment has been made, the parties shall apply to the Court for approval of the same as having been prudent decisions. The institution so chosen shall thereupon consent to the jurisdiction of the MDL Court acknowledging that it alone has the obligation to manage the settlement fund. Periodic reports should be made to the Court of the interest earned, distributions made, and other matters involving the status of administration. Its management shall thereafter be subject to review by the MDL Court.

F. The defendants will make the initial payment into the settlement fund within 30 days of confirmation that the enrollment levels (85% of the death plaintiffs, 75% of the non-death plaintiffs and 12,000 claimants) have been reached. Thereafter, defendants will pay the additional sums set forth in 3B into the settlement fund within 30 days of confirmation for each 1% incremental increase in death and/or non-death enrollees. If, upon completion of the Program, the aggregate sum of the awards of the Special Master is less than the settlement fund, the difference and interest on that difference shall remain in the fund for disposition as provided in 18F.

#### 4. WAIVERS AND RELEASES

A. In consideration for the plaintiffs and claimants agreeing to enter the Program and surrendering their rights to litigate their cases or claims, the defendants unconditionally waive all defenses in law and equity which they have or may have to those cases or claims except as otherwise described in this document.

B. In consideration for the defendants waiving the defenses they have in law and equity and agreeing to enter the Program, the plaintiffs and claimants unconditionally release whatever rights they have or may have against the defendants, their agents, servants, employees, officers and directors and those who acted in concert with them together with their respective insurers. In addition, no plaintiff shall enter the Program until his or her counsel shall have executed a stipulation of dismissal with prejudice. The same shall be given to counsel for the defendants who are to hold it in escrow and who are authorized to file it only upon the determination by the Medical Panel that the claim does not qualify for payment or upon confirmation by the Special Master that the claim has been dismissed under Section 7 or, if the claim is held by the Medical Panel to qualify for payment, only upon payment of the award.

C. By entering this Program, the plaintiffs, claimants and defendants acknowledge that decisions to be made by the Medical Panel and Special Master may be ones with which they disagree. They further acknowledge that this eventuality is part of the Program and they accept it.

D. All releases from plaintiffs or claimants given under this Program shall be given to Janssen Pharmaceutica, Inc., Johnson & Johnson, Janssen Research Foundation, Janssen Pharmaceutica, N.V., Robert Wood Johnson Pharmaceutical Research Institute, and all entities and persons related to them.

## 5. MEDICAL RECORDS SUBMISSIONS

A. The parties shall agree upon and submit with the Consent Order whatever claim form is appropriate to be completed by those persons who seek payment under this Program. The completed claim form shall set forth the medical condition or injury for which compensation is sought as a result of Propulsid ingestion. The Special Master shall make those forms available to those persons and, once completed, to the parties and shall determine whether the completed forms adequately provide the information required under this Program.

B. The attorneys representing the plaintiffs and the attorneys representing the claimants shall have the right to collect and submit the medical records called for by the Program through their own efforts. They shall also have the right to use any common medical records collecting service which may be established for purposes of collecting the medical records and submitting them to the Medical Panel. The defendants reserve the right to submit medical records which it has gathered on plaintiffs and claimants and to examine the medical records submitted on their behalf. The attorneys representing the plaintiffs and the attorneys representing the claimants also have the right to examine the medical records submitted by the defendants. All parties have the right to argue to the Special Master whether the Medical Records Submission has been accomplished in accordance with the requirements of the Program. All records of claimants who opt in which were at any time collected or to be collected by claimants and/or defendants shall be promptly placed in the depository. Claimants and defendants by placing their records in the depository consent to review of such records, including medical records, by parties' attorneys,

medical experts, consultants, depository staff, the Medical Panel, the Court and the Special Master, but such records shall otherwise remain confidential in conformity with HIPPA.

C. In the event the Medical Panel finds that a plaintiff or claimant is not entitled to payment under this Program, a \$250 payment to defray costs paid for the medical records or assembly of same by the attorney for the plaintiff or the attorney for the claimant shall be paid from the administrative fund pursuant to Section 16B. It is understood that the only records required to be submitted to qualify for the \$250 reimbursement is a single medical or pharmacy prescription record indicating Propulsid use and a medical condition or injury which the claimant has attributed to Propulsid in Section 5A. This aspect of the Program and the payment described are only for the benefit of actual Propulsid users.

#### **6. PAYMENTS BY CATEGORY**

A. Once the Medical Panel has determined that a person is eligible for payment and has identified the category, the Special Master shall decide what sum shall be awarded. In so deciding, the Special Master shall give consideration to those factors relevant to the payment of damages for the particular person under commonly accepted rights of recovery.

B. It is not possible to determine what payment will be made to any plaintiff or claimant until: (1) the Medical Panel has made its determinations of eligibility and, if eligible, the category of eligibility and (2) the Special Master has determined the amount to be paid. The final amount of these payments will not be determinable until the claims of all who enroll in this Program have been decided.

C. The Special Master is not to consider the amount of the settlement fund or the exhaustion of that fund as a limitation in making any award. In the event the total sums to be awarded to those persons found eligible under the Program exceed the total sum available in the settlement fund, the awards shall be reduced and paid on a pro rata basis. All relevant liens shall have been resolved before any payments are made under this Program.

D. The parties will explore whether it is feasible to make a partial payment of a sum awarded to a plaintiff or claimant in advance of the final determination of the total sums to be awarded to all plaintiffs and claimants and the timing of release and indemnity agreement. If such a payment is made it will be recognized as a partial, not final payment, all subject to Section 6(B).

#### **7. MEDICAL PANEL**

A plaintiff or Claimant shall have 120 days from the date of service by the PSC of notice that the Program's minimum enrollment levels have been reached, or 120 days from the date a plaintiff or Claimant serves an Enrollment Form, whichever is later, to serve a Claim Form. In extraordinary circumstances in cases where the attorney for plaintiffs or Claimants has more than 100 such clients and has not submitted all the Claim Forms in a timely manner, the Special Master may grant a reasonable extension of time to complete submission of the remaining Claim

Forms. If a plaintiff or claimant fails to submit the required medical records within 60 days after he or she has completed the claim form described in Section 5(A), that person's claim shall be dismissed with prejudice. No further action is to be taken on it and no litigation may be commenced or maintained to attempt to pursue that claim. However, if a plaintiff or claimant has made a good faith effort to secure records, then the period will be extended for 60 days, upon application to the Special Master. If the Special Master has determined that a good faith effort has been made to obtain the medical records, but they are still not available, the Panel may review the records available, but the possible recovery must still meet the requirements of the guidelines. If a plaintiff or Claimant fails to submit the required medical records within the 60 day extension and the Special Master has determined that the plaintiff or Claimant has not made a good faith effort to secure records, that person's claim shall be dismissed with prejudice. No further action is to be taken on it and no litigation may be commenced or maintained to attempt to pursue that claim. Once the required medical records have been received in the medical records depository, they shall be given to the Medical Panel together with the claim forms so that the Panel can decide whether the claim is eligible for payment.

## 8. ADMINISTRATION

The parties intend that the administration of this Program shall be conducted in a manner designed to expedite medical records collections, the analysis of claims and the determination whether they qualify for acceptance or rejection.

## 9. MDL ASSESSMENT

A. This settlement Program is MDL 1355 work product, developed and agreed upon through court-ordered negotiations between Janssen Pharmaceutica and the Plaintiffs' Steering Committee in MDL 1355. The use of this Program for settlement purposes constitutes consent by the plaintiff or a claimant under a tolling agreement to pay 6% of the gross amount of any award issued by the Special Master. This is pursuant to the common benefit trust fund established by Pretrial Order No. 16 in MDL 1355. This order is available on the court's website, <http://propulsid.laed.uscourt.gov>

B. The Plaintiffs' Steering Committee (PSC) shall provide any MDL plaintiff's or MDL claimant's attorney who is bound by the 6% arrangement, but who does not enter this Program upon written notice to the PSC, a trial package which will consist of:

1. Liability briefs;
2. Depositions of Janssen, J&J and MDL-PSC experts and of Janssen and J&J consultants, employees and former employees;
3. Generic expert reports;
4. Stipulations from the defendants as to use of depositions at trial;

5. Demonstrative evidence developed by PSC to-date;
6. Deposition excerpts and outlines developed by the PSC to date;
7. Selective documents and any accompanying stipulations on cd rom;
8. Access to the PSC-MDL depository upon fourteen (14) days certified mail notice to the PSC for fourteen (14) months from written notice that claimant will not participate in this Program, but requests a trial package.
9. Additionally, attorneys may request a trial transcript of a Propulsid trial at additional cost payable to plaintiff's attorneys who participated in such trial(s).

C. PSC represents that it has no other obligation, to furnish additional materials, assist in further discovery, trial preparation or trial. PSC represents that the trial package forms a material basis for claimant's case but is not a complete preparation. That preparation must be completed by claimant's attorneys based on the attorney's judgment and at claimant's expense and it is claimant's sole obligation to select, use or supplement the material in the trial package. The package may not be shared, copied or communicated in any manner to any other attorney or claimant.

#### **10. NO ADMISSION OF LIABILITY**

Neither Janssen's agreement to, nor participation in, this Program constitutes an admission of liability to any person or other entity by Janssen Pharmaceutica Inc. or any corporate entity or person related to it, e.g., Johnson & Johnson, Janssen Research Foundation, Janssen Pharmaceutica, N.V.

#### **11. CONFIDENTIALITY**

The amount and fact of settlements reached under this Program are confidential, except as may be required by statute, court order, court rule, or the settlement approval process where court approval of a settlement is required by law in the relevant jurisdiction. Agreement to, and maintenance of, confidentiality are material terms of any settlement reached. An exemplar release will be jointly prepared by the parties. See Section 24 for additional provisions relating to confidentiality.

#### **12. INFORMATION REQUIRED TO CONSUMMATE SETTLEMENT**

A list of the information which must be provided to the attorneys for Janssen before a settlement check is delivered will be provided to the PSC.

### 13. PARTICIPATION

A. Death cases / cardiac arrest cases (Tiers I and II) - In these cases, the parties may provide within 60 days of the deadline for serving all required medical records confidential memoranda (simultaneously submitted at a date set by the two physician panel), explaining the party's contention as to a plaintiff's or claimant's qualification or non-qualification under the Program and the category. Memoranda are limited to five (5) pages and exhibits attached may be abstracts or full documents not to exceed thirty (30) pages. There shall be no submission by either party of expert reports or affidavits in support of or in opposition to qualification or category.

B. Tier III – In these cases no memoranda of the type described in Section 13(A) shall be permitted and the Medical Panel shall rest its decision on the medical records submitted. A one page summary may be submitted to point out the supporting documents and expedite medical review. There shall be no submission by either party of expert reports or affidavits in support of or in opposition to qualification or category.

C. In the event that the two medical panelists cannot agree on a plaintiff's or claimant's qualification or non-qualification and, if qualified, in which category, a third panel member will be selected on a rotating basis by the Special Master to cast the deciding vote. The rotation shall be a panelist appointed by the PSC, then a panelist appointed by the defense and so on in that order.

D. All decisions of the Medical Panel are final and not appealable. See Section 2(D). All cases submitted to the Panel for decision will be decided within 45 days of submission to the Panel. In the event a third panelist is required, a decision will be forthcoming within 30 additional days. The deadlines may be extended by the Special Master upon showing of good cause. Thereafter, the Special Master may call for additional records such as birth, death, and/or marriage certificates, economic loss evidence (tax returns, pay stubs, benefits books income and support records) which must be furnished within 30 days of the request. The Special Master shall tentatively decide the level of payment to plaintiff claimant within 45 days of submission to him by the Medical Panel of its decision that a case qualifies for payment. This shall be subject to revision under Section 18(D). It shall remain confidential until a final determination is made by the Special Master. The final award by the Special Master is conclusive and non-appealable.

E. Except as is set forth in Section 1(A)(B) defendants, by engaging in this Program waive and dismiss with prejudice all defenses of liability as to participating claimants such as statutes of limitation and repose, jurisdiction, venue, mitigation, comparative/contributory negligence, assumption of risk, independent intervening cause and products' liability, specific defenses such as state of the art, no safe alternative design, preemption, FDA and other regulatory approval, learned intermediary, etc. The defendants do not waive the defenses that the plaintiff or claimant was not exposed to Propulsid and that the claimed event was not caused or contributed to by use of Propulsid, as those requirements are necessary for any payment to be made pursuant to Tiers I, II and III in Exhibit A.

#### 14. STANDARDS TO BE USED

A finding for eligibility to enter a defined category does not require findings of medical certainty but only findings that something is more probable than not. The following standards should be used by the Medical Panel or upon inquiries by it to the Special Master:

A. "But for" tests – whether harm (death, cardiac arrest or serious tachycardia ventricular arrhythmia) would more probably have occurred or not because of the user's ingestion of Propulsid.

B. Concurrent cause and substantial factor. Cause-in-fact is usually a "but for" inquiry which tests whether the harm would not have occurred "but for" the use of Propulsid, and the substantial factor inquiry is an alternative method of analysis used when two or more combined causes may be present. Thus, where there may be concurrent causes of an injury, the proper inquiry is whether the product in question was a substantial factor in bringing about the harm or injuries. A party's act may be a substantial factor in bringing about the harm or injury when the harm would not have occurred without the product's use.

C. The package literature identifies certain medications as contraindicated for use while Propulsid is being taken and identifies the presence of certain conditions as a contraindication for the use of Propulsid. The existence of such events in any claimant's case does not of itself entitle the claimant to a recovery nor deny a claimant a recovery.

D. Any legal interpretation of these standards may be referred by the Medical Panel to the Special Master on a case by case basis. The interpretation of the Special Master will be final and unappealable and will be rendered only in writing within 3 calendar days of the request.

#### 15. MEMBERS OF MEDICAL PANELS

A. Six physicians, licensed in Louisiana and in good standing, or a lesser or greater number agreed to by the PSC and Janssen, will be chosen 50% by Janssen and 50% by the PSC. The physicians must be recognized board certified cardiologists, electrophysiologists or internists who have had substantial training and substantial experience treating cardiac problems or physicians board certified in a specialty dedicated to the treatment of cardiovascular diseases or board certified physicians who have documented substantial training and experience treating cardiac problems. They may be active, semi-retired or retired. Each side will have veto over the other side's selection. A member of each physician group shall sit on a panel to determine category eligibility and non-eligibility. Once the members of the Medical Panel have been chosen and no veto as to their selection has been exercised, the parties shall have no ex parte contact with those members. In the event the parties agree to any training to be done with the members of the Medical Panel, that teaching will be done jointly.

B. If either party believes that a member of the Medical Panel is consistently disregarding the Program's provisions respecting requirements for eligibility or non-eligibility, the PSC and defense counsel shall meet and confer to address the issue and, absent a resolution, either party

may bring the matter to the attention of MDL Court which shall have the authority to remove the physician from the Medical Panel. The MDL Court will interview the challenged panelist in camera and, if necessary, remove the panelist. No counsel may be present at such hearing and the hearing and Order of the Court will be final and non-appealable and sealed in the record. That physician's replacement, if the MDL Court removes a physician, shall then be designated by the party who originally chose that physician. This provision is not intended to create an appeal system for occasional eligibility or non-eligibility decisions with which one party disagrees.

#### 16. CLAIMANT ENTRANTS' BENEFITS

Any claimant electing to enter this Program, in addition to potential entry into a category and level of payment, receives the following benefits:

- A. Waiver of defenses by the defendants to claimant's claim as provided in Section 13(E).
- B. Payment of \$250 pursuant to Section 5(C) to defray costs of obtaining the medical records described in Exhibit A, Section 2, if the Medical Panel finds, following a review of a sufficient amount of those records, that there is no entitlement to payment under the settlement fund.
- C. Establishment of a settlement process and fund.
- D. Expedited review and acceptance or rejection of claims.
- E. Evaluation of claimant's medical records and circumstances by at least (2) two qualified physicians without cost to claimant.

#### 17. ADMINISTRATIVE FUND

- A. The following are examples of administrative expenses:
  - 1. Depository costs (including storage, document or electronic retention, equipment, paralegal and other employee salaries, rent and utilities).
  - 2. Payment of certain medical records pursuant to Section 5(C).
  - 3. Payment of fees to members of Medical Panels.
  - 4. Payment of fees to Special Master.
  - 5. Reimbursement of miscellaneous expenses agreed to by PSC and defendant.
  - 6. If the enrollments required to start the Program are reached, reimbursement of reasonable out of pocket expenses incurred by PSC in

enrolling participants in the Program. The proposed expenses must be submitted to defense counsel in advance and agreed to within five days of their submission. If such agreement is not reached, the Special Master shall decide whether the expenses or any part of them shall be paid from The Administrative Fund.

- B. No administrative funds may be used to pay claims.
- C. Excess refunded to defendant.
- D. Defendant to supply \$15,000,000 after the Program has become effective pursuant to Section 1(B) and the Special Master has been appointed by the MDL Court and has accepted that assignment.
- E. Account to be administered in New Orleans by financial institution of defendants' selection with interest accrual on balances. Periodic reports should be made to the Court of the interest earned, distributions made, and other matters involving the status of administration. Interest on those payments to be added to the administrative fund. Interest (after payment of taxes) on the \$15,000,000 or any portion thereof shall be added, if needed, to the Administrative Fund to meet its obligations. If not needed, the balance of any principal and/or interest shall be returned to the defendants.
- F. All category claims to be determined within 3 months of records submission.
- G. PSC and Janssen to establish joint medical and other records depository in New Orleans and each assign a paralegal knowledgeable of the case to administer. Salary to be agreed upon and paid by the fund.

#### 18. SETTLEMENT FUND

- A. The Settlement Fund will be established pursuant to Section 3(E).
- B. Claims verification and payment milestones (to be detailed in documents submitted with Consent Order).
- C. Claims to be paid within an agreed time after verification compliance.
- D. Each claim to escrow a reserve and escrow paid if total claims do not exceed fund.
- E. If claims exceed amount in Settlement Fund then the Fund will be distributed pro rata (based on claims value) after all claims have been processed.
- F. If there are excess funds left in the Settlement Fund after payment of all awards made by the Special Master, the parties shall meet and confer about appropriate ways in which those funds can be used in a manner consistent with mediation and resolution of Propulsid litigation.

Until such time as the Special Master shall have made an award pursuant to this Program, the Settlement Fund remains the property of the defendants, for the benefit of Propulsid claimants, subject to distribution only pursuant to the terms of this Program.

**19. ATTORNEY FEES:**

In addition to the 6% fee due to the PSC pursuant to Section 9, the PCS shall be entitled to an additional fee and the parties have agreed that the PSC may seek and recover such attorneys' fees and costs. It is agreed that the PSC's work product and efforts to date have been responsible for developing and creating the Settlement Program, and that the PSC's future involvement in the administration of the Settlement Program will confer a substantial benefit on all of its participants. The parties recognize that *Sprague v. Ticonic Nat'l Bank*, 307 U.S. 161 (1939), *Mills v. Electric Auto-Lite Co.*, 396 U.S. 375, 393 (1970) and other well established authority, permit the district court to grant such an award based upon its inherent powers of equity and that such award shall be paid separately and in addition to the assessment already authorized by the Court in PTO No. 16. Consistent with this jurisprudence, the defendants have agreed to pay and not contest any award for attorneys' fees and costs in the amount up to and including, \$22,500,000, but defendants will not pay any sum in excess of that amount. The PSC is required to petition for such an award and the amount and propriety of the same shall be determined by the court upon recommendation of the Special Master. The defendants will pay that award within 30 days of receipt of the Order of the MDL Court rendering that award. If a dispute arises thereafter as to division of the attorney's fee award or challenges relating to payment of the attorneys' fees, the MDL Court, Judge Fallon, shall direct the PSC as to appropriate escrow (escrow depository to be selected by the PSC) of the fund, partial payment to entitled attorneys and, in the MDL Court's sole discretion, determine the appropriate division of fees, which decision shall be final and non-appealable. It is understood that once defendants deliver the fee check to the PSC, they have no further responsibility whatsoever for the payment of any legal fees to any firm, person or legal entity and that the MDL Court's fee order may not be reviewed pursuant to FRCP Rule 60 or on any other basis.

**20. SETTLEMENT WITH AN INDEPENDENT PARTY REQUIREMENT**

The plaintiff or claimant must provide the amount of any settlement reached with an entity other than Janssen, the identity of the party with whom or which the settlement has been reached and information about the pendency of any case or claim by him or her involving use of Propulsid.

**21. IMPLEMENTATION OF THE PROGRAM**

The PSC and the defendants will submit to this court within 30 days of the execution of this document a proposed Consent Order and other mutually satisfactory documents establishing the Program and seeking approval of this court of the same. The Order will incorporate the terms of this document and such additional matters as the Court may direct or the parties agree are necessary to the implementation and management of the Program. The parties do not presently

foresee that matters not addressed in this document but which are necessary for inclusion in a Consent Order cannot be resolved between them. The PSC shall have 180 days from the date of that Consent Order to secure the required number of written consents from counsel for plaintiffs and persons under tolling agreements, as set forth in Section 1, and to present them to counsel for the defendants. If the requirements set forth in Section 1 have not been satisfied within the 180 day minimum enrollment period, this agreement shall terminate and The Program will not be implemented unless otherwise agreed by the parties.

To the consent order should be attached an agreed-upon enrollment form to be signed by counsel for plaintiffs and counsel for tolling agreement claimants and the claim form to be signed by plaintiffs and tolling agreement claimants when they submit their medical records. In particular, language in the consent order will have to make clear that all plaintiffs and the tolling agreement claimants, i.e., persons not presently subject to the jurisdiction of the MDL Court, and the defendants accept the jurisdiction of that Court and that the Court is, by their consent: a) empowered to enter an order terminating plaintiffs' and claimants' rights to sue the defendants if they fail to submit the medical records within the time set forth in the term sheet or if the Medical Panel does not decide that they are entitled to compensation and, b) empowered to enter an order authorizing the Special Master to pay from the settlement fund any award that he makes in favor of such a plaintiff or claimant consistent with this agreement.

## **22. ADMINISTRATION OF THE PROGRAM**

The parties will include in the Consent Order appropriate provisions for the management of the Program including duties to be performed by the Special Master, proposed fee arrangement for members of the Medical Panel, as well as how they should fulfill their duties, reports to the PSC and the defendants about claims submissions under the Program and all other administrative matters designed to accomplish the purposes set forth in Section 8. All plaintiffs or claimants who participate in the Program stipulate and agree that the Program is and will remain subject to the jurisdiction of the MDL Court until all proceedings under the Program have been concluded.

## **23. MEDICAL PANEL REVIEW PROCEDURES.**

The parties shall prepare a joint written protocol for the members of the Medical Panel to follow in the performance of their responsibilities. The protocol shall cover the administrative issues respecting the work of the Medical Panel, e.g., time limits for case reviews, adherence to the Settlement Requirements set forth in Exhibit A, etc.

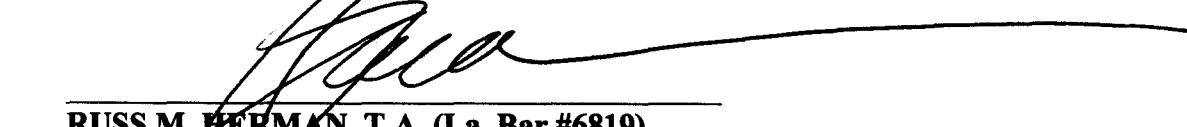
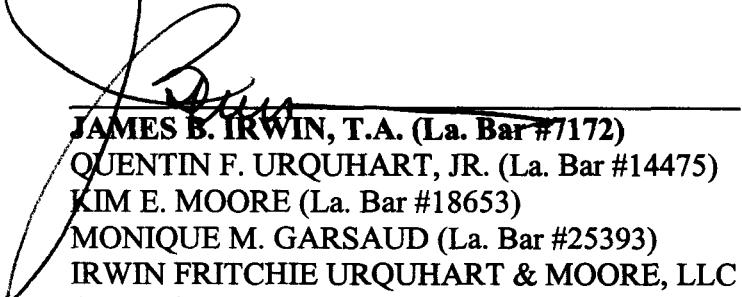
## **24. PUBLIC STATEMENTS ABOUT THIS SETTLEMENT**

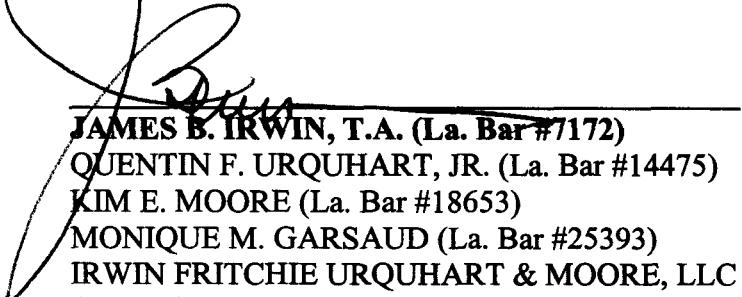
The parties shall prepare a joint statement describing this settlement and the Program established herein and shall agree upon the manner and timing of distribution. This shall be the only statement to be distributed except as the parties may further agree. The parties and their counsel agree that they shall make no other public statement. These conditions are material

conditions to this agreement. This will not constitute a restriction on plaintiffs' or claimants' attorneys' communication with their clients about this matter except to the extent there is use of the media or any other public forum for that purpose. The contents of this term sheet shall not be made public by any party until the consent order described in Section 21 has been entered. See Section 11 for additional confidentiality requirements.

Executed in triplicate original on this the 30<sup>th</sup> day of April, 2004.

This Term Sheet supercedes the Term Sheet executed by the parties on January 30, 2004 and March 11, 2004.

  
**RUSS M. HERMAN, T.A. (La. Bar #6819)**  
LEONARD A. DAVIS, #14190  
JAMES C. KLUCK, #7451  
HERMAN, MATHIS, CASEY, KITCHENS & GEREL, LLP  
820 O'Keefe Avenue  
New Orleans, Louisiana 70113  
Phone: (504) 581-4892, Fax: (504) 561-6024  
**LIAISON COUNSEL FOR PLAINTIFFS**  


  
**JAMES B. IRWIN, T.A. (La. Bar #7172)**  
QUENTIN F. URQUHART, JR. (La. Bar #14475)  
KIM E. MOORE (La. Bar #18653)  
MONIQUE M. GARSAUD (La. Bar #25393)  
IRWIN FRITCHIE URQUHART & MOORE, LLC  
400 Poydras Street, Suite 2700  
New Orleans, Louisiana 70130  
Phone: (504) 310-2100  
Fax: (504) 310-2101  
**LIAISON COUNSEL FOR Defendants,**  
**JANSSEN PHARMACEUTICA INC. AND JOHNSON & JOHNSON**

DRINKER, BIDDLE & REATH LLP  
THOMAS F. CAMPION  
SUSAN M. SHARKO  
500 Campus Drive  
Florham Park, NJ 07932-1047  
Phone: (973) 549-7300  
Fax: (973) 360-9831

**-and-**

DRINKER, BIDDLE & REATH, LLP  
CHARLES F. PREUSS  
DONALD F. ZIMMER, JR.  
50 Fremont Street, 20<sup>th</sup> Floor  
San Francisco, CA 94105-2235  
Phone: (415) 591-7500  
Fax: (415) 591-7510  
**CO-LEAD COUNSEL FOR Defendants,**  
**JANSEN PHARMACEUTICA INC. AND**  
**JOHNSON & JOHNSON**

## EXHIBIT A

### SETTLEMENT REQUIREMENTS APPLICABLE TO ALL CASES

1. FACTUAL REQUIREMENTS. There must be credible evidence from the medical records that each of the following is more likely than not:

A. **EVENT** - The plaintiff or the plaintiff's decedent (hereinafter referred to jointly as the "person"), must have had an event. An event is defined as death, cardiac arrest or primary tachycardic ventricular arrhythmia. Primary tachycardic ventricular arrhythmia is limited to primary, sustained ventricular tachycardia, ventricular fibrillation or torsades de pointes.

Primary is further defined as a symptomatic ventricular arrhythmia (ventricular tachycardia or ventricular fibrillation) that occurs in the absence of a concurrently documented causative factor that precipitated the arrhythmia, including, but not limited to, acute myocardial infarction, active myocardial ischemia and decompensated congestive heart failure. Conditions such as hypokalemia or hypomagnesemia documented at the time of the arrhythmia may be considered by the Medical Panel to be causative factors.

Sustained is further defined as continuous ventricular tachycardia 1) of at least 10 seconds duration, or 2) requiring termination through therapeutic intervention by precordial thump, electrical cardioversion or medication, or 3) with associated symptoms of hemodynamic deterioration such as syncope, presyncope (distinct feeling of impending loss of consciousness which does not eventuate) or shock. Neither dizziness nor lightheadedness is considered an associated symptom, nor is chest pain which precedes the arrhythmic event.

B. **INGESTION** - The person must have ingested Propulsid within 72 hours of the event or, in the case of death, within 72 hours of the arrhythmia that directly resulted in the subsequent death.

## 2. MEDICAL RECORD REQUIREMENTS

A. **For a person who was age 12 or older at the time of the event.** The person's relevant medical records as defined in subpart D below, immediately preceding the date of the event must be provided to the Medical Panel.

B. **For a person who was under age 12 at the time of the event.** The person's relevant medical records from birth through the date of the event must be provided to the Medical Panel.

C. **For all people.** The person's relevant medical records from the time of the event until death, or until 60 days before the time the case is submitted under The Program, whichever is applicable. These records are of particular importance in the evaluation process.

D. **Relevant records.** For the purposes of this Program, the following are a person's relevant medical records. Time periods are deemed appropriately modified where the person was less than twelve years of age at the time of the event. The PSC and J&J may agree to order supplemental records at the expense of the administrative expense fund:

- (1) **The one-year period before the event.** Full records for any kind of medical care in the one year preceding the event (doctor, hospital, pharmacy, ambulance, therapy, etc.).
- (2) **The three-year period before the event.**
  - (a) Full hospital records for hospitalizations.
  - (b) All electrocardiogram, holter monitor, and other cardiac monitoring or testing records for the three years before the event.
  - (c) Physician records from the person's primary care physician or physicians (if any), cardiologist or cardiologists (if any), gastroenterologists and/or pediatrician or pediatricians (if any).
  - (d) Prescription records for all prescribed medications.
- (3) **The ten-year period before the event.**
  - (a) Full hospital records where cardiac concerns are implicated.
  - (b) Full hospital records where GI concerns are implicated.
  - (c) Full EKG's.

## **2. SETTLEMENT CATEGORIES**

### **TIER I: DEATH CASES**

1. The medical records and other factual information are more consistent with a primary tachycardic ventricular arrhythmia being the cause of death than any other reasonable cause, and
2. Death would not have occurred but for decedent's use of Propulsid, or in those cases where there was more than one contributory cause to the death, Propulsid was a substantial factor as defined in Section 14(B), and
3. The autopsy findings, if any, are more consistent with a primary tachycardic ventricular arrhythmia being the cause of death than any other reasonable cause.

**TIER II: NONFATAL CARDIAC ARREST  
LEVEL A**

1. No documented evidence of previous cardiac arrest, myocardial ischemia or myocardial infarction and no documentation that patient was at high risk for cardiac arrest before taking Propulsid, and
2. The arrest is more consistent with a primary tachycardic ventricular arrhythmia being the cause than any other reasonable cause, and
3. The arrest would not have occurred but for the patient's use of Propulsid, or in those cases where there was more than one contributory cause to the arrest, Propulsid was a substantial factor as defined in Section 14(B), and
4. The arrest was witnessed by a health care provider or required therapy such as CPR or defibrillation or was documented on an EKG or monitor.

**LEVEL B**

1. Some risk factors for cardiac arrest present, but no prior history of cardiac arrest and
2. The arrest is more consistent with a primary serious tachycardic ventricular arrhythmia being the cause than any other reasonable cause, and
3. The arrest would not have occurred but for the patient's use of Propulsid, or in those cases where there was more than one contributory cause to the arrest, Propulsid was a substantial factor as defined in Section 14(B), and
4. Medical Treatment was obtained following the arrest.

**TIER III: PRIMARY TACHYCARDIC VENTRICULAR ARRHYTHMIA**

1. The primary tachycardic ventricular arrhythmia must be documented in a rhythm strip, or there is documentation in the patient's medical records that the rhythm strip demonstrated the same, and

2. The primary tachycardic ventricular arrhythmia (including Torsades de Pointe) is more consistent with the patient's use of Propulsid than any other reasonable cause, and
3. The primary tachycardic ventricular arrhythmia would not have occurred but for the patient's use of Propulsid, or in those cases where there was more than one contributory cause to the primary tachycardic ventricular arrhythmia, Propulsid was a substantial factor as defined in Section 14 (B), and
4. Required medical attention in the form of a hospital evaluation or ER visit for treatment of the arrhythmia.

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